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August 3, 1998

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street SW  
Washington, DC 20204

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**Section 403(r)(6) Notification**

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

**Helps Promote a Calming Effect**

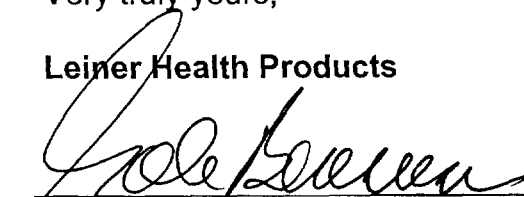
**KaValerian™ is a unique herbal supplement complex that helps promote a calming effect on the body. Kavalactones (the active compounds of kava) act as natural muscle relaxants that may promote a feeling of serenity. Valerian has been used historically as a natural aid for relaxation. Magnesium is essential for proper nerve and muscle function, and Lecithin may also increase the absorption of other nutrients.**

on the following product:

**YourLife® KaValerian™**

Very truly yours,

**Leiner Health Products**

  
Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs  
William Cochran, Regulatory Affairs Associate